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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROSENTHAL, CASEY S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,289	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Casey Rosenthal	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 5/6/2004.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 40, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer region comprising polyisocyanates, classified in class 424, subclass 422.

   II. Claim 41, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer region comprising unsaturated polymers, classified in class 424, subclass 422.

   III. Claim 42, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer region comprising amine content polymers, classified in class 424, subclass 422.

   IV. Claim 43, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer region comprising acrylates, classified in class 424, subclass 422.

   V. Claim 44, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer

region comprising polymers containing hydrogen bonding groups, classified in class 424, subclass 422.

VI. Claim 45, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer region comprising inorganic polymers, classified in class 424, subclass 422.

VII. Claims 46-48, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a drug; and a primer region comprising silane coupling agents, titanates, or zirconates classified in class 424, subclass 422.

VIII. Claims 51-52, drawn to an implantable device comprising a substrate having a surface which includes a chromium oxide layer; a primer layer including a polymer; and a reservoir layer comprising a polymer and a drug classified in class 424, subclass 422.

IX. Claim 53, drawn to an implantable device comprising a coating, wherein the coating comprises a reservoir region comprising a polymer and a drug; and a primer region, classified in class 424, subclass 422.

X. Claim 55, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including polyisocyanates, classified in class 604, subclass 1+.

XI. Claim 56, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including unsaturated polymers, classified in class 604, subclass 1+.

XII. Claim 57, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including amine content polymers, classified in class 604, subclass 1+.

XIII. Claim 58, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including acrylates, classified in class 604, subclass 1+.

XIV. Claim 59, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including polymers containing hydrogen bonding groups, classified in class 604, subclass 1+.

XV. Claim 61, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including inorganic polymers, classified in class 604, subclass 1+.

XVI. Claim 62-64, drawn to a stent comprising a coating, wherein the coating comprises: a reservoir region comprising a drug; and a primer region including silane coupling agents, titanates, or zirconates, classified in class 604, subclass 1+.

XVII. Claim 64, drawn to a stent comprising: a substrate having oxide, anionic, or hydroxyl moieties or groups; a primer region including a polymer; and a reservoir region comprising a drug, classified in class 604, subclass 1+.

2. Claims 37-39 and 49-50 link(s) inventions I-VII and claim 54 link(s) inventions X-XVI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 37-39, 49-50 and 54. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other because:

4. Inventions I-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I-XVII are each unrelated due to various elements including types of devices, coatings, and differing materials used in the primer region and reservoir regions. Thus, groups I-XVII are patentably distinct from one another for the reasons explained below in paragraph 5 of this restriction.

5. Teaching in the art indicates that an implantable device as in groups I-IX can be a multitude of objects other than a stent as in groups X-XVII including catheters, pacemakers, intraocular lenses, shunts, and knee implants therefore the implantable devices of I-IX are not equivalent to the stents of X-XVII. The implantable devices of groups I-VII and IX comprise a coating whereas the implantable device of group VIII does not comprise a coating but rather includes a chromium oxide layer. Although, inventions I-VII and IX all include a coating the reservoir region differs in that inventions I-VII includes a drug in the reservoir region whereas invention IX includes both a drug and a polymer in the reservoir region. Thus, inventions I-VII and IX are not equivalent. Similarly, the stent of inventions X-XVI comprise a coating whereas the stent of invention XVII does not comprise a coating but rather includes a substrate having oxide, anionic, or hydroxyl moieties or groups on the outer surface. Inventions I-VII differ from one another in that they each include a different material in the primer region such that group I comprises polyisocyanates, group II comprises unsaturated polymers, group III comprises amine content polymers, group IV comprises acrylates, group V comprises polymers containing hydrogen groups, group VI comprises inorganic polymers, and

group VII comprises silane coupling agents, titanates, or zirconates. Each of these materials is chemically distinct because each will yield different structures, functions, reactivities, and physiochemical properties. Similarly, groups X-XVI differ in the same manner; each group differs in that they include a different material in the primer region such that group X comprises polyisocyanates, group XI comprises unsaturated polymers, group XII comprises amine content polymers, group XIII comprises acrylates, group XIV comprises polymers containing hydrogen groups, group XV comprises inorganic polymers, and group XVI comprises silane coupling agents, titanates, or zirconates. For the same reason sited above, groups X-XVI are also not equivalent. Therefore, inventions I-XVII have different issues regarding patentability and enablement. Art anticipating one group would not anticipate or render obvious another group. Each invention requires completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. As such, this creates an undue search burden.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for each individual Group of I-XVII is not required for the remaining Groups of I-XVII, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. In addition to an election of one of groups I-XVII above, restriction is further required under 35 U.S.C. 121 as follows:

10. **In the event that applicant elects Group IX, the following election of species is required.** This application contains claims directed to the following patentably distinct species of the claimed invention:

a. A primer material chosen from the following:

i. Poly(hydroxyvalerate)

ii. Poly(L-lactic acid)

iii. Polycaprolactone

iv. Poly(lactide-co-glycolide)

v. Poly(hydroxybutyrate)

vi. Poly(hydroxybutyrate-co-valerate)

vii. Polydioxanone

viii. Polyorthoesters

ix. Polyanhydrides

x. Poly(glycolic acid)

xi. Poly(D,L-lactic acid)

xii. Poly(glycolic acid-co-trimethylene carbonate)

xiii. Polyphosphoesters

xiv. Polyphosphoester urethanes

xv. Poly(amino acids)

xvi. Cyanoacrylates

xvii. Poly(trimethylene carbonates)

xviii. Poly(iminocarbonate)

xix. Copoly(ether-esters)

xx. Polyalkylene oxalates

xxi. Polyphosphazenes

xxii. Fibrin

xxiii. Fibrinogen

xxiv. Cellulose

xxv. Starch

xxvi. Collagen

xxvii. Hyaluronic acid

xxviii. Polyurethanes

xxix. Silicones

xxx. Polyesters

xxxi. Polyolefins

xxxii. Polyisobutylene,

xxxiii. Ethylene-alphaolefin copolymers

xxxiv. Acrylic polymers and copolymers

xxxv. Vinyl halide polymers and copolymers

xxxvi. Polyvinyl chloride

xxxvii. Polyvinyl ethers,

xxxviii. Polyvinyl methyl ether

xxxix. Polyvinylidene halides

xl. Polyvinylidene fluoride,

xli. Polyvinylidene chloride

xlii. Polyacrylonitrile

xliii. Polyvinyl ketones

xliv. Polyvinyl aromatics

xlv. Polystyrene

xlvi. Polyvinyl esters

xlvii. Polyvinyl acetate

xlviii. Copolymers of vinyl monomers with each other and olefins,

xlix. Ethylene-methyl methacrylate copolymers

l. Acrylonitrile-styrene copolymers

li. ABS resins

lii. Ethylene-vinyl acetate copolymers

liii. Polyamides

liv. Nylon 66

lv. Polycaprolactam

lvi. Alkyd resins

lvii. Polycarbonates

lviii. Polyoxymethylenes

lix. Polyimides

lx. Polyethers

lxi. Epoxy resins

lxii. Rayon

lxiii. Rayon-triacetate

lxiv. Cellulose

lxv. Cellulose acetate

lxvi. Cellulose butyrate,

lxvii. Cellulose acetate butyrate

lxviii. Cellophane

lxix. Cellulose nitrate

lxx. Cellulose propionate

lxxi. Cellulose ethers

lxxii. Carboxymethyl cellulose

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 53 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Due to the complexity of the action, examiner submitted the Election Restriction in writing in lieu of calling applicant's attorney.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

15. Applicant is also reminded that a 1-month (not less than 30 days) shortened statutory period will be set for response when a written restriction is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Rosenthal whose telephone number is 571-212-6097. The examiner can normally be reached on 8:00 am - 5:00 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-212-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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